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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/054,854	01/25/2002	Alfred Schaufler	2002-0092A	8581

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EXAMINER	
MOHAMED, ABDEL A	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 11/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/054,854	SCHAUFLER, ALFRED	
	Examiner	Art Unit	
	Abdel A. Mohamed	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) *35-40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 4/22/02, 11/06/02, 03/10/03
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

ACKNOWLEDGMENT OF PRIORITY, PRELIMINARY AMENDMENT, IDS, ELECTION, AMENDMENT, STATUS OF THE APPLICATION AND CLAIMS

1. Acknowledgement is made of Applicant's claim priority based on Denmark Application Number PA 2001 00135 having a filing date of 1/25/01. Receipt is acknowledged of papers submitted under 35 U.S.C. § 119, which papers have been placed of record in the file. The preliminary amendment, the information disclosure statement (IDS) and Form PTO-1449, election and amendment filed 5/2/02, 4/22/02, 11/6/02, 3/10/03 and 8/9/04, respectively are acknowledged, entered and considered. In view of Applicant's request claims 31 and 34 have been amended. Claims 1-40 are now pending in the application (See Rule 126 below).

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are presented, they must be renumbered consecutively beginning with number next following the highest numbered claims previously presented. In the instant case, after claim 38, the next claim is claim 40. Thus, claim 39 is missing. Therefore, in accordance with Rule 1.126, claim 40 is renumbered as claim 39, and claim 41 renumbered as claim 40. Hence, claims 1-40 are now pending in the application.

ELECTION WITHOUT TRAVERSE

2. Applicant's election without traverse of Group I (claims 1-34) in the reply filed on 8/9/04 is acknowledged. Hence, claims 35-40 are withdrawn as non-elected inventions and the Office action is directed to the merits of claims 1-34 as *per* elected invention.

OBJECTION TO TRADEMARKS AND THEIR USE

3. The use of the trademarks "TachoComb®", "TachoComb® H", and "Tachotop®" have been noted in this application. The trademarks have not been capitalized, they should be capitalized wherever they appear and be accompanied by the generic terminology. Although, the use of trademarks are permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in a manner, which might adversely affect their validity as trademarks.

Further, the specification, which specifies the generic terminology should include, published product information sufficient to show that the generic terminology or the generic description are inherent in the article referred by the trademarks. These description requirements are made because the nature and composition of articles denoted by trademarks can change and affect the adequacy of the disclosure.

CLAIMS REJECTION-35 U.S.C. § 112 2nd PARAGRAPH

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 7, 8, 10 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 7, 8 and 10, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 10 recites the broad recitation 1-4, and the claim also recites such as 1.5 to 3.5, such as 2.5 to 3.0, which is the narrower statement of the range/limitation.

Claim 11 recites the limitation "the lactic acid" in line 1. There is insufficient antecedent basis for this limitation in claim 11 or claim 5, or claim 3, or claim 2 or claim 1. Amendment of the claim to depend on claim 7 is suggested.

CLAIMS REJECTION-35 U.S.C. § 103(a)

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kokai Japanese Unexamined Patent Publication No. 7-59812 (Publication date 3/17/95) taken with GB Patent No. 1 292 326 and WO 99/13902.

The translation (provided by Applicant) of Kokai Japanese unexamined patent publication No. 7-59812 teaches as disclosed in the abstract that the use of a wound cover material comprised of a collagen sponge structural body having a so-called honeycomb structure that has air bubbles controlled to a diameter within the range of 50-2000 μm, (overlapping the claimed ranges claimed by Applicant), said air bubbles communicating straight from one surface to the other surface, and each of said air bubbles being substantially independent from each other. On page 5, the prior art clearly shows that it is within skill of the art to which this invention pertains to control the diameter of the air bubbles by regulating the amount of collagen and concentration of ammonia gas, thereby making it possible to change the pore size of the collagen sponge. The preferred concentration of collagen is about 0.1-10%, and the concentration of ammonia gas is about 100 ppm in order to neutralize a solution having a collagen concentration of 1% and during the ammonia neutralization process, the container is allowed to stand for 12 hours at room temperature. Following standing,

after washing the formed gel overnight with running water, freeze-drying was performed to obtain sponge having a pore size of 300-500 μm (See also, embodiments 1-6) as directed to claims 1-3, 10, 12, 18-27 and 34.

The Japanese unexamined patent publication No. 7-59812 differs from claims 1-34 in not teaching a) obtaining collagen from tendons having a sponge density of 1 to 10 mg/cm^3, b) use of or organic acids, and c) the selection of specific temperatures, pHs, viscosity, elasticity, and density. However, GB patent No. 1 292 326 teaches a method and apparatus for the preparation of collagen dispersions with a view of to their applications, wherein by "dispersion of collagen" is meant a normal or colloidal or gel of collagen in water or the relevant organic medium. The preparation of spongy collagenic articles can be effected from dispersion or gels of collagen by using lyophilization techniques. A sub-atmospheric pressure exists in the treatment chamber, in which the suspension is transformed into a dispersion by stirring and controlled acidification by means of a mineral or organic acid such as lactic acid (See pages 1-3) as directed to claims 6, 7, 9 and 11. On example 2, the reference discloses a collagenic dispersion free of air bubbles having lactic acid content of 0.5%, collagen content of 2.5%, the density of the dispersion is 0.80 and its viscosity 37 poises at the sliding velocity of 5.5 sec^{-1} as directed to claims 11, 15, 17, 20-24 and 29. Furthermore, as acknowledged on page 3, lines 16 to 29, the reference of WO 99/1392 discloses the preparation of sponge from bovine tendons by dispersing at pH in the range of about 2 to 3 into a solvent such as lactic acid and mixing with a high level of agitation using a blender, so as to produce microfibers of collagen, and lyophilization of a collagen dispersion having sponge density of about 0.1 mg/cm^3 and a pore size ranges from about 10 μm to about 500 μm (See e.g., pages 7-8 and 10) as directed to claims 4-10 and 14-16.

In regard to specific pHs, temperatures, diameters, dimensions, percentage of collagen content, viscosity, duration of time for storage, homogenizing, neutralizing and drying, percentage of lactic acid, gel content, water content and others; the combined teachings of the prior art as shown above clearly discloses ranges which overlaps with claimed pHs, temperatures, diameters, dimensions, contents of collagen, gels, lactic acid, viscosity, and duration of times as recited in the claims. Further, it is conventional and within the ordinary skill in the art to which this invention pertains to determine the optimization values of causes effective variables such as these process parameters. Thus, the instant invention's method of preparing a collagen sponge, which falls within the scope of the combined teachings of the cited prior method of preparation of collagen sponge would have been *prima facie* obvious from said prior art combined disclosure to a person of the ordinary skill in the art because in the absence of sufficient objective factual evidence or unexpected results to the contrary, Applicant's claims are directed to optimization of an "art recognized variables" which is well within the purview of one of ordinary skill in the art, *In re Boesch*, 617 f. 2d 272, 205 USPQ 215 (CCPA 1980).

CONCLUSION AND FUTURE CORRSPONDANCE

6. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abdel A. Mohamed whose telephone number is (571) 272 0955. The examiner can normally be reached on First Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (571) 272 0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JON WEBER
SUPERVISORY PATENT EXAMINER

Mohamed/AAM
10/29/04